

ETCTN Patient Enrollment Information Page

1. Introduction

The Oncology Patient Enrollment Network (OPEN) is the web-based registration system for patient enrollments onto NCI-sponsored clinical trials. The system is integrated with the Cancer Trials Support Unit (CTSU) for regulatory and roster data, and with Theradex's registration/randomization system for patient registration/randomization. OPEN provides the ability to enroll patients on a 24/7 basis. Access to the OPEN system is controlled through the CTEP Identity and Access Management (CTEP-IAM) system and through role assignments in the CTSU Roster Update Management System (RUMS) or the CTSU Roster Maintenance application.

All **new** trials opened under the ETCTN program will use OPEN for the enrollment of patients. For slot reservations and cohort management, OPEN will contain a link to Theradex's Interactive Web Response System (IWRS), providing a seamless integration between the two systems. Furthermore, patient enrollment data entered in OPEN and IWRS will automatically transfer to the NCI's clinical data management system, Medidata Rave, so data does not need to be entered more than once.

All trials activated **prior to** the implementation of the ETCTN program will continue to follow their existing procedures for patient enrollment, although some of these trials may transition into OPEN.

Each protocol document will include information on which enrollment system is used for that trial.

2. Use of OPEN and IWRS

2.1 User Requirements

To use OPEN/IWRS, the following user requirements must be met:

- Active CTEP registration with the credentials necessary to access secure NCI/CTSU Information Technology (IT) systems. Refer to [Registration Procedures and CTSU Website Access](#) page for more information.
- Registered in the Registration and Credential Repository (RCR) with an Associate Plus, Non-physician Investigator or Investigator registration type to enroll patients.
- Have the role of Registrar on an ETCTN Lead or Participating Organization roster to enroll patients or request slot reservations; refer to [Rosters and Roles for ETCTN Participants \(Institution Rosters and Person Rosters\) Information Page](#) for more information.
- Be identified as the Client Admin with Theradex for the study to approve slot reservations or access cohort management.
- Have regulatory approval for the conduct of the study at their site; refer to [ETCTN Regulatory Processing Information Page](#) for more information.

2.2 Training

There are several resources related to the use of OPEN and IWRS for patient enrollments.

Refer to the OPEN section of the CTSU members' website (username and password required) for an overview of OPEN. Both this page and the OPEN website welcome screen (no password required) contain OPEN-related training materials.

Theradex has developed a *Slot Reservations and Cohort Management User Guide*, which is available on the NCI page of the [Theradex](#) website under *IWRS for ETCTN studies*. This link to the Theradex website is also on the OPEN Home Page.

3. For Questions and Support

For questions about OPEN or the entire patient enrollment process, contact the CTSU Help Desk:

- CTSU Help Desk: 1-888-823-5923; CTSUContakt@westat.com; CTSU Help Desk hours are 9:00 am – 6:00 pm ET Monday-Friday (excluding holidays).

For questions about the use of IWRS for slot reservations, contact the Theradex Help Desk:

- Theradex Help Desk: 609-619-7802 or Theradex main number 609-799-7580; CTMSSupport@theradex.com.